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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,195	09/12/2000	Howard R. Levin	3659-17	6619
7590	12/30/2003		EXAMINER	
Nixon & Vanderhye PC 1100 North Glebe Road 8th Floor Arlington, VA 22201-4714			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)
	09/660,195	LEVIN ET AL.
	Examiner Leslie R. Deak	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 April 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9-11, and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,838,865 to Flank in view of US 6,171,253 to Bullister et al, further in view of US 6,272,930 to Crozafon et al. Flank discloses a blood handling cartridge with inlet tubing 11, pressure measuring devices 15, 24 that may operate piezoelectrically and comprises electrical connections 117, 118 (FIG 15, column 8, lines 42-57), pump segment 10 that defines a blood passage that is engaged by a pump, and outlet tubing 11' (see FIG 3, column 5, lines 45-67). The system disclosed by Flank further includes a dialyzer/blood filter 27 in fluid communication with and connected to the blood cartridge (see FIG 3), and a pressure gauge 24a in the filtered fluid passage 28a (see FIG 4). Flank further discloses that the cassette has fastening devices, which may include latches, that fasten the cassette to the pump drive housing (column 4, lines 9-15). Applicant's recitation of a second cassette with a second loop is obvious over the Flank device, since the Flank device includes a second loop, and it is within the skill of a worker in the art to separate formerly integral units. See MPEP 2144.04. With regard to applicant's recitation of the manner in which the pressure sensor operates (producing an electric voltage signal), and disposal of the device, a recitation of the intended use of

the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Flank discloses the apparatus as claimed with the exception of the pressure sensors having a tubular shape, mounted within the blood channel. Bullister discloses a flow-through pressure sensor in order to precisely measure fluid pressure in a chamber without affecting the flow of fluid through the chamber. The sensor 18 is attached to a flow vessel, and includes a hemocompatible cannula tube 30 through which the fluid is channeled (column 2, lines 31-39, 60-64, FIGS 1 and 2). The pressure sensor further includes a diaphragm 34 that is displaced according to the fluid pressure within the flow passage. The flexing of the diaphragm is measured by strain gauges 42 that produce an electrical voltage signal as the diaphragm is deformed under varying amounts of pressure (column 3, lines 16-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the flush-mounted flow through pressure sensors disclosed by Bullister in the extracorporeal blood handling cartridge disclosed by Flank in order to measure the pressure of the fluid flowing through the passageways without disturbing actual fluid flow, as taught by Bullister. Furthermore, there is no size limit directed to the pressure sensor disclosed by Bullister, and the pressure sensor may be adapted to measure the pressure within a cylindrical blood filter, such as that disclosed by Flank. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time of invention to adapt the pressure sensor disclosed by Bullister to measure the pressure of blood flowing through the filter in the system disclosed by Flank, since changing the size of a recited component involves only routine skill in the art.

The Flank and Bullister device disclose the apparatus as claimed with the exception of the size of the pressure sensor. While a change in size is generally held to be within the capability of one of ordinary skill in the art, Crozafon discloses a flow-through pressure sensor wherein the face of the pressure sensor is substantially flush with the tube element defined by the body of the pressure measuring device, which is contiguous with the flow channel of a tube that transports fluid from a human body (see column 2, lines 42-60, FIGS 1, 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adjust the size and location of the flow-through pressure sensor disclosed by Flank and Bullister in order to accurately measure the pressure of the fluid flowing through the tube in a short time (see column 2, lines 10-15).

With regard to claim 7, Flank discloses the connection of the hemofilter/dialyzer with the blood cartridge, but not mounted to the cartridge. It would have been obvious to one of ordinary skill in the art at the time of invention to move the hemofilter/dialyzer to a location on the cartridge, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With regard to claim 14, the modified Flank/Bullister device fails to disclose a third pressure sensor located in the blood return passage. However, It has been held

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that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

3. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,838,865 to Flank et al in view of US 6,171,253 to Bullister et al, in view of US 6,272,930 to Crozafon, further in view of US 4,229,299 to Savits et al. The modified Flank device discloses the apparatus as claimed with the exception of transparent blood passages and the pressure sensor embedded in the filter. Savits discloses a pump means for dialysis treatment with tubing that forms blood passageways and a filtration device. The use of transparent tubing for blood processing machines is well known in the art of extracorporeal blood treatment, and is incorporated in the Savits device (column 8, lines 32-35). Therefore, it would have been obvious to one of ordinary skill in the art to provide the modified Flank extracorporeal blood processing device with conventional transparent tubing in order to monitor the flow of blood through the system. Furthermore, Savits discloses the use of a hollow-fiber blood filter, which is well known in the art of blood treatment, and allows for removal of impurities from the blood (column 5, lines 4-7). The tubular pressure sensor disclosed by Bullister is capable of measuring fluid through any tubular conduit, and may be reduced in size in order to be incorporated within the hollow fiber of a semipermeable filter in order to measure the pressure of the diasylate fluid flowing within the hollow fibers of the Savits blood filter. Therefore, it would have been obvious to one of ordinary skill in the art to use the hollow fiber filter disclosed by Savits in the modified Flank device in order to allow the tubular pressure sensor disclosed by Bullister to measure the pressure of the fluid flowing

through the filtration fluid side of the blood processing circuit, without adversely affecting the flow thereof, as taught by Bullister.

Response to Amendment/Arguments

4. Applicant's arguments filed 2 October 2003 have been fully considered but they are not persuasive.
5. With regard to applicant's argument that Flank does not support a tube loop, see FIG 2, wherein the tubing loop is mounted on the cartridge. Furthermore, Flank discloses that the cartridge may be fastened into a tube pump driving element, which indicates that the tubing segments engage a pump for pumping. See column 4, lines 9-15. With regard to the separable cassettes, it is within the skill of a worker in the art to separate formerly integral units. See MPEP 2144.04.
6. With regard to the pressure sensor arguments, moving the pressure sensor from the dialyzer segment of the Flank device to the cassette of the Flank device is a mere obvious rearrangement of the parts of the device. See MPEP 2144.04. Furthermore, applicant merely claims a flow-through pressure sensor that is "substantially" the same diameter as the interior of the blood passage, which is illustrated by both Bullister and Crozafon. Still further, Crozafon specifically discloses that his device is designed to measure pressure of a liquid flowing in a tube that has been extracted from the human body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to replace the pressure sensor of the Flank device (which flows liquid extracted from the human body through a tube) with the Crozafon pressure sensor, in

order to obtain more accurate pressure readings without artifact from changing vessel sizes. The Savits device is relied upon to introduce transparent tubing and a hollow fiber flow device, through which pressure may be measured by the Bullister/Crozafon pressure sensors.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

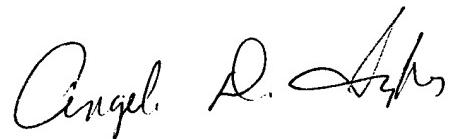
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-305-3590
for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is 703-308-
0873.



December 18, 2003

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700